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Iowa Board of Pharmacy News

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Prescription Monitoring Program Update

As of June 30, 2012, 3,352 prescribers and 1,308 pharmacists have registered to use the Iowa prescription monitoring program (PMP). Between January 1, 2012 and June 30, 2012, prescribers submitted 50,257 requests for data. During the same period, pharmacists submitted 4,955 requests. If this trend continues during the remainder of 2012, the number of requests from prescribers will increase 41% from 2011 and the number of requests from pharmacists will increase 21% from 2011. The program is continuing to reduce the incidence of patients who utilize multiple pharmacies and multiple prescribers to obtain controlled substances. The number of patients who received Schedule II, III, and IV controlled substances from five or more prescribers or pharmacies decreased 53% between 2009 and 2011, from 3,293 incidents in 2009 to 1,769 in 2011. This downward trend is continuing in 2012. Between January 1, 2012 and June 30, 2012, 830 incidents were reported.

The following changes have been made to the Iowa PMP:

- Effective July 1, 2012, prescribers and pharmacists may authorize agents to register for the program and access and retrieve PMP data on their behalf. A prescriber or pharmacist may authorize no more than three agents. Please visit the following Web site for more information: *www.state.ia.us/ibpe/pmp/pmp_info.html.*
- Beginning January 1, 2013, pharmacies will be required to submit controlled substance dispensing information to the PMP on not-less-than a **weekly** basis.
- Nonresident (out-of-state) pharmacies licensed in Iowa will be required to report to the Iowa PMP beginning January 1, 2013.

CPE Monitor

The Iowa Board of Pharmacy encourages pharmacists and pharmacy technicians to obtain their National Association of Boards of Pharmacy® (NABP®) e-Profile ID by setting up their e-Profile and registering for CPE Monitor™. Even if a licensee has already created his or her e-Profile, completion of CPE Monitor registration is necessary in order to fully activate his or her e-Profile ID and enable the CPE activity monitoring and tracking capability. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited CPE providers will require licensees to submit their NABP e-Profile ID and date of birth (MMDD) in order to obtain credit for CPE activities. Currently, more than 90 ACPE-accredited providers are actively transmitting CPE data through CPE Monitor. Pharmacists and pharmacy technicians may visit *www.MyCPEmonitor.net* to set up their e-Profile, register for CPE Monitor, and obtain their e-Profile ID.

Pharmacist Continuing Professional Development

Continuing professional development (CPD) is a self-directed, practitioner-centered, outcomes-based model that is designed to meet the learning needs of the individual pharmacist. This approach has been implemented using a variety of models and regulatory frameworks in various health professions and countries and is now being explored by the Iowa Board of Pharmacy. The Board and the Iowa Pharmacy Association have recently formed a CPD Task Force to look at using CPD as a means for pharmacist re-licensure. The task force has two goals: (1) to create a mechanism for pharmacists to seek re-licensure by means of CPD in lieu of, or in addition to, traditional continuing education (CE) requirements; and (2) to develop components of a CPD portfolio and a systematic rubric to evaluate CPD as a method of re-licensure for practicing pharmacists. From July 2012 through June 2013, a select group of Iowa pharmacists will adopt CPD as a method for documenting CE and other learning activities. The selected pharmacists will receive education regarding CPD; guidance on using the portfolio to reflect, plan, evaluate, and record their learning activities; and information about the evaluation rubric that will be used to assess their portfolios. Due to the timeline of this project, the evaluation will occur after one year, but the project will continue for the entire two-year license renewal period. An interim progress report of the CPD Task Force will be presented to the Board in July 2013. Currently, there are approximately four states evaluating the use of CPD. In addition, ACPE has created a CPD Task Force, which closely monitors the advancement of CPD nationally.

Board Licensing and Registration Statistics – Summer 2012

- Iowa-licensed pharmacists: 5,802 (3,363 residing in Iowa)
- Registered, nationally certified pharmacy technicians: 4,129
- Registered, uncertified pharmacy technicians (including trainees): 1,213

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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- Total technicians: 5,342
- Registered pharmacy support persons: 1,234
- Pharmacist-Interns: 1,547
- Total support staff: 8,123
- Iowa pharmacies: 1,510
- Nonresident (out-of-state) pharmacies: 567
- Controlled Substances Act registrants (includes pharmacies): 16,026
- Wholesalers (in state and nonresident): 1,430

New Compliance Officer Territories

Effective August 1, 2012, the Board's compliance officers cover the following areas of Iowa:

- **Curt Gerhold:** Benton, Cedar, Davis, Henry, Iowa, Jefferson, Johnson, Jones, Keokuk, Lee, Mahaska, Poweshiek, Tama, Van Buren, Wapello, and Washington, **and** the following zip codes in Linn County: 52213, 52314, 52214, 52404, and 52405.
- **Mark Mather:** Black Hawk, Bremer, Buchanan, Butler, Cerro Gordo, Chickasaw, Floyd, Franklin, Howard, Mitchell, and Worth, **and** the following zip codes in Linn County: 52233, 52302, 52401, 52402, 52403, and 52411.
- **Sue Mears:** Boone, Buena Vista, Cherokee, Clay, Dallas, Dickinson, Lyon, O'Brien, Osceola, Plymouth, Pocahontas, Sioux, and Webster, **and** the following zip codes in Polk County: 50111, 50131, 50265, 50266, 50309, and 50324.
- **Jennifer O'Toole:** Adams, Appanoose, Clarke, Decatur, Fremont, Jasper, Lucas, Marion, Mills, Monroe, Montgomery, Page, Pottawattamie, Ringgold, Taylor, Union, and Wayne, **and** the following zip codes in Polk County: 50310, 50311, 50313, and 50315.
- **Jean Rhodes:** Emmet, Grundy, Hamilton, Hancock, Hardin, Humboldt, Kossuth, Marshall, Palo Alto, Story, Winnebago, and Wright, **and** the following zip codes in Polk County: 50009, 50021, 50023, 50226, 50312, 50314, 50322, 50325, and 50327.
- **Jennifer Tiffany:** Adair, Audubon, Calhoun, Carroll, Cass, Crawford, Greene, Guthrie, Harrison, Ida, Madison, Monona, Sac, Shelby, Warren, and Woodbury, **and** the following zip codes in Polk County: 50316, 50317, 50320, and 50321.
- **Jim Wolfe:** Allamakee, Clayton, Clinton, Delaware, Des Moines, Dubuque, Fayette, Jackson, Louisa, Muscatine, Scott, and Winneshiek.

Next Board Meeting

The Board plans to hold its next meeting on November 8-9, 2012, at the Board office in Des Moines, IA. Please contact the Board office at 515/281-5944 to confirm.

Board Web Site

Please visit the Board's Web site at *www.state.ia.us/ibpe/.*

Board Mission

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code §155A.2(1).

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